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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,881	11/27/2000	Michel L.P.M. Verhoeven	P-4566	4027
28390	7590	03/10/2005	EXAMINER	
GHERBI, SUZETTE JAIME J				
ART UNIT		PAPER NUMBER		
3738				

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/721,881	VERHOEVEN, MICHEL L.P.M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Suzette J Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 December 2004.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 4-7 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

1. Applicant RCE dated 12/15/04 has been received in application serial number 09/721,881.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. 6,110,483 in view of Elton 5,160,790 and further in view of Isner 5,830,879. Whitbourne et al. discloses the invention as claimed comprising: A radially expandable stent comprising a wire having a substantially uniform hydrogel coating layer thereon; wherein the layer has an average coating thickness of about 0.01 micrometers to about 25 micrometers; and wherein the layer has a biologically active agent, a biocompatible, hydrophilic surface. See col. 1, lines 45-47; col 2, lines 6-9, 25-31, 34-35, 40, 53-67; col. 6, lines 28-58; col 7, lines 15-17 and col. 8, lines 19-21 however Whitbourne does not specifically say "dry coating thickness". Isner teaches

that hydrogel coatings can have and "dry" coating thickness in the ranges of between 0.2-0.3 microns (see col. 7, lines 24-34) and that these coating can; be applied to stents. However Whitbourn and Isner et al. do not specify that *the coating has a standard deviation of no greater than 10 percent*. Elton teaches a hydrogel coating that can be applied to a stent in a uniform continuous thickness (col. 4, lines 10-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the coatings of Whitbourne et al. and Isner and apply the coating *with no greater than 10 percent standard deviation* because Whitbourne et al. and Isner discloses that the coatings of the invention may be thin on the order of 2-100 microns and 0.02-0.3 microns and that the coating is a continuous thin layer (see col. 4, line 18).

#### ***Response to Arguments***

4. Applicant's arguments filed 12 have been fully considered but they are not persuasive. 12/15/04. Applicant first contends that Whitbourne et al does not disclose a radially expandable stent or a substantially uniform hydrogel coating layer. (a) It is known to those skilled in the art that "all" stents are capable of being radially expandable even self-expandable stents. A balloon catheter is capable of being inserted and a radial pressure exerted to expand the stent. It is also noted that this limitation in the preamble breathes no life into the claim. (b) Applicant has defined the phrase "substantially uniform coating" (see page 4 of specification) as "...that the wire surface is completely covered by a coating....". The stent of Whitbourne et al. does meet the definition of this phrase because Whitbourne et al. states that the stent can be dipped,

sprayed, brushed, wiped ect (see col. 2, lines 60-62) and nowhere does Whitbourne et al. state that only sections or parts are coated therefore rational discloses that the entire stent has a substantially uniform coating. (c) With regards to the limitation "standard deviation" the examiner of record has found no definition in the specification as to the meaning and or criticality of this limitation. The objective of the combined references above *is* to provide a completely covered stents with a thin hydrogel coatings and the microns described in Isner and Whitbourne fall within the claimed range (see claim 2) of applicant's invention.

5. Applicant goes on to contend that Elton's "composition is uniformly" dispersed. It is thought that applicant has mis-interpreted the prior office action. As stated above Whitbourne et al. teaches, "substantially uniform" as defined by applicants specification. The Elton reference is merely reiterating that by varying the composition of the coating any reasonable coating thickness can be achieved which is why it would be obvious to manufacture a stent (as currently claimed but not explained by applicant) "having a relative standard deviation of no greater than about 10 percent".

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

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7. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi

04 March 2004